CALIFORNIA DEVICE MANUFACTURING LICENSE APPLICATION—NEW AND RENEWING

Date received	License number	Payment type	Amount
			$

PLEASE DO NOT WRITE ABOVE THIS LINE

Please provide all requested information. Incomplete applications will be returned.

1. Manufacturer Information

Name and/or DBA

Address (number, street)	City	State	ZIP code
		California	

Contact person	Telephone number	FAX number	E-mail/website URL

2. Correspondence address (number, street, P.O. box), if applicable | City | State | ZIP code

Correspondence address (number, street, P.O. box), if applicable | City | State | ZIP code

3. FDA FEI (CFN) | President/CEO | Corporate owner | Management representative

4. Please indicate the type of license application.
☐ New application ☐ License renewal ☐ Relocation ☐ Change in ownership ☐ Change in both location and ownership

5. If change in ownership, has there also been a ***change in management staff with executive responsibility***? ☐ Yes ☐ No

6. Stage of manufacture at date of application (check all that apply)
☐ Manufacturing products ☐ Design development ☐ Design validation ☐ Pre-production design transfer ☐ Other

7. Intended device destination (check all that apply)
☐ Investigational studies ☐ Export market ☐ California distribution ☐ U.S. distribution ☐ Other

8. Please check each product area that applies to the devices manufactured.

☐ 862. Clinical chemistry and clinical toxicology
☐ 864. Hematology and pathology
☐ 866. Immunology and microbiology
☐ 868. Anesthesiology
☐ 870. Cardiovascular
☐ 872. Dental
☐ 874. Ear, nose, and throat
☐ 876. Gastroenterology/urology
☐ 878. General and plastic surgery
☐ 880. General hospital and personal use
☐ 882. Neurological
☐ 884. Obstetrical and gynecological
☐ 886. Opthalmic
☐ 888. Orthopedic
☐ 890. Physical medicine
☐ 892. Radiology
☐ Unclassified devices

List types of classified and/or unclassified manufactured devices in the spaces below. Use additional sheets as necessary.

Federal Classification Title	Classification (Check One) I	II	III

9. Please identify the manufacturing processes employed or planned in the manufacture of the devices listed above, and if activities will be done at this location (in-house) or by contract. List other processes using additional sheets, if necessary.

Processes/Activities	In-house	Contract	Processes/Activities	In-house	Contract
Sterilization			Repackaging/relabeling		
Software development			Remanufacturing/refurbishing		
Circuit board assembly			Tissue/cell culture		
Lyophilization			Others		
Antigen/antibodies					

10. Signature and title of person(s) making this license application and date signed.

Signature	Title	Date

Signature	Title	Date

CALIFORNIA DEVICE MANUFACTURING LICENSE APPLICATION—NEW AND RENEWING INSTRUCTIONS

A separate application is required for each place of business. Please complete or amend so that all information requested is current and complete. If the information requested is not applicable to your facility, write N/A in the space. If it is not available, write "not available" in the space. ***Include a check with the current year 2003 fee of $440.53*** with this application.

Please make checks payable to the: CALIFORNIA DEPARTMENT OF HEALTH SERVICES. A late fee of $10.00 must be added to the renewal fee for all renewal license applications received by the department more than 30 days after the license expiration date. Applications that are unsigned, incomplete, or that are not accompanied by all applicable fees cannot be processed. The following are further instructions on how to complete this application:

1. ***Manufacturer Information—Name, Address, and Contact:*** List the name of the product manufacturer whose name will appear on the license issued by the Department of Health Services. Include the street address of the manufacturing facility to be licensed. List the name, telephone number, fax number, and electronic mail address (if available) of the designated contact person who is responsible for answering questions regarding this application. The URL is the firm's Internet web site address, if available.

2. ***Correspondence Address*:** List the address where all official correspondence, including the manufacturing license, should be sent if different from that of the manufacturing address.

3. ***Other information:*** The **FDA Registration** is the registration number issued by the Food and Drug Administration for this manufacturing address. State law requires that every manufacturing facility register with the Secretary of Health and Human Services (FDA). If the registration has been applied for but has not been completed, please indicate "PENDING." The ***President/CEO*** is the highest-ranking individual responsible for all activities at this facility. The ***Corporate Owner***, if applicable, is the name of the Parent Corporation of the firm to be licensed. The ***Management Representative*** is the name of the person appointed to establish and maintain quality system requirements as required by Quality System Regulation [21CFR 820.20(b)(3)]. [See websites: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/ShowCFR.cfm?FR=820.20/ and http://www.fda.gov/cdrh/dsma/cgmphome.html#contents/, as well as http://www.fda.gov/cdrh/devadvice/ and http://www.fda.gov/cdrh/ and http://www.fda.gov/cdrh/popular.html/ and http://www.fda.gov/cdrh/fedregin.html/ and http://www.fda.gov/cdrh/devadvice/ and http://www.fda.gov/cdrh/guidance.html/ and http://www.fda.gov/cdrh/thirdparty/].

4. ***Type of License Application****:* Check the appropriate box. Firms not previously licensed should check the box labeled "New." Firms that are renewing their license should check the box labeled "License Renewal." Previously licensed firms that have undergone a change in either person or owners to be licensed (ownership) or place (relocation) should indicate this by checking the appropriate box. These firms may require a site inspection before the license is issued.

5. ***Management with Executive Responsibility:*** This is management as defined in the Quality System Regulation/GMP Section: 21 CFR 820. [See http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/ShowCFR.cfm?CFRPart=820.] Please indicate whether the Management with Executive Responsibility has changed, as a result of a *Change in Ownership*.

6. ***Stage of Manufacture:*** Check the most appropriate stage of manufacturing for the devices at this facility.

7. ***Distribution:*** Check all appropriate boxes indicating the intended distribution of devices that are currently or will be manufactured at this facility.

8. ***Types of Products Manufactured****:* Check each product area box that applies to the devices manufactured or to be manufactured. For each medical device product, list the federal classification name and classification category (I, II, or III) as listed in 21 CFR, Sections 862 through 892. [See http://www.access.gpo.gov/nara/cfr/waisidx_00/21cfrv8_00.html and http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm.] If not known or if thought to be unclassified, please provide your best description for each device. Use additional sheets if necessary.

9. ***Manufacturing Processes at this Facility:*** Check if any of the indicated processes will be done at this location (in-house) or by a contract manufacturer (Contract). Leave line blank if the indicated process will not be used in the manufacture of listed devices. List additional processes or methods as needed herein or on additional sheets if necessary.

10. ***Please sign, date, and state title of signatory.*** Enclose the appropriate licensing fee and mail or ship to:

Regular U. S. Mail:
Department of Health Services
Food and Drug Branch—Medical Device Desk
P. O. Box 942832, Mail Stop 357
Sacramento, CA 94234-0006

or

Express Mail (Physical Address):
Department of Health Services
Food and Drug Branch—Medical Device Desk
601 North Seventh Street, Mail Stop 357
Sacramento, CA 95814

If you have any further questions, please contact the Food and Drug Branch, Device and Drug License Desk, at (916) 445-5224 or visit our web site at: http://www.dhs.ca.gov/fdb/. Thank you.